JUL 1 3 2007

K070577

510 (K) SUMMARY

Date of Summary
July 12, 2007

Product Name:
On the Go Sharps Transport and Disposal *with Safe-Lock™*

Sponsor & Manufacturer:
MedPort, LLC
23 Acorn Street
Providence, RI 02903

Correspondent:
Fran WhitE
MDC Associates, LLC
163 Cabot Street
Beverly, MA 01915

Substantially Equivalent Device:
K041153
Sharps Away™ Locking Disposal Cup

Product Description:
On the Go Sharps Container is designed as a single use device that holds a single contaminated sharp. The contaminated sharp is placed into the container and immediately locked using the Safe-Lock Lid. Once closed the device can not be opened thereby minimizing the risk of contamination.

Intended Use:

The On the Go Sharps Transport & Disposal is intended as a single use, needle protection device. The device is intended to hold only one contaminated sharp. The device is designed for use with Insulin syringes. It is intended to be sold Over-the-Counter for personal use only; not for professional use or use in professional healthcare facilities.

Performance Characteristics:

Simulated use studies confirmed that people with different educational background can successfully use the On The Go Sharps Container in accordance with instructions provided.

Once locked the device can not be opened. The contaminated sharp does not penetrate the plastic, thereby providing a safe method for transporting contaminated sharps to a site for disposal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2007

MEDport, Incorporated
C/O Ms. Fran White
Regulatory Consultant
MDC Associates
163 Cabot Street
Beverly, Massachusetts 01915

Re: K070577
Trade/Device Name: On the Go Sharps Transport & Disposal with Safe-Lock™ Lid Single Use Sharps Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: June 28, 2007
Received: July 2, 2007

Dear Ms. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K070577

Device Name: On the Go Sharps Transport & Disposal *with Safe-Lock™ lid*
Single use sharps container

Indications For Use:

The On the Go Sharps Transport & Disposal is intended as a single use, needle protection device. The device is intended to hold only one contaminated sharp. The device is designed for use with Insulin syringes. It is intended to be sold Over-the-Counter for personal use only; not for professional use or use in professional healthcare facilities.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shirley A Murphy MD
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K070577